

1K970911

**510(k) Summary**

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Device Proprietary Name: Lee Plate

Device Common Name: Small Bone Plate

Classification Name: Bone Plate 872.4760

Name of Submitter: Howmedica Leibinger Inc.

Contact Person: Kristyn Waski  
Quality Assurance/Regulatory Affairs Engineer  
Howmedica Leibinger Inc.  
14540 Beltwood Pkwy., East  
Dallas, TX 75244  
Telephone: (972) 392-3636  
Fax: (972) 392-7258

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**Summary:**

This submission describes a bone plate intended for use in internal fixation of corrective osteotomies to the symphysis region of the mandible (genioplasty procedures). It is designed to provide fixation to an advanced anterior mandibular bone segment. Screw holes allow for attachment to the anterior mandible and the osteotomized segment. 1.7 mm and 2.0 mm diameter screws are used to attach the plate to bone.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Profil-O-Plastic Chinplate [K862534 Paulus Titanium Mini Bone Plates and Screws]. Both plates are intended for use in the fixation of corrective mandibular osteotomies. Both plates are manufactured from commercially pure titanium. Both the Lee Plate and the Profil-O-Plastic Plates are contoured plates with screw holes to allow for attachment to mandibular bone. The operational principle and indications and contraindications are equivalent for both of these devices.